



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0329]

Dilip Patel; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is denying a request for a hearing submitted by Dilip Patel and is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Patel for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Patel was convicted of a conspiracy to commit a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act and that the conduct underlying the conviction undermines the process for the regulation of drugs. In determining the appropriateness and period of Patel's debarment, FDA considered the relevant factors listed in the FD&C Act. Patel failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: The order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Any application for termination of debarment by Patel under section 306(d) of the FD&C Act (application) may be submitted as follows:

Electronic Submissions

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. An application submitted electronically, including attachments, to

<https://www.regulations.gov> will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on <https://www.regulations.gov>.

- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: Your application must include the Docket No. FDA-2009-N-0329. An application will be placed in the docket and, unless submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your application and you must identify this information as "confidential." Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240-402-5931.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(II) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(II)) permits FDA to debar an individual if it finds: (1) that the individual has been convicted of a conspiracy to commit a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act and (2) that the type of conduct which served as the basis for the conviction undermines the process for the regulation of drugs.

On April 24, 2007, Patel pled guilty to one count of conspiracy to distribute misbranded and adulterated drugs, in violation of 18 U.S.C. 371. On December 9, 2010, the U.S. District Court for the District of New Jersey entered the conviction, sentenced Patel to 2 years of probation, and imposed a \$3,000 fine. Patel's conviction stemmed from his employment at Able Laboratories, Inc. (Able), where he was a Supervisor of Analytical Control and later a Quality Control Manager in the Quality Control Department. Patel and his co-conspirators conspired and agreed with others to cause the introduction of misbranded and adulterated drugs into interstate commerce with an intent to defraud and mislead the United States, in violation of sections 301(a) and 303(a)(2) of the FD&C Act (21 U.S.C. 331(a) and 333(a)(2)). Specifically, according to the criminal information to which he pled guilty, Patel supervised the falsification and manipulation of assay test results for atenolol, a prescription medication for cardiac conditions, and he directed a subordinate chemist to falsify and manipulate dissolution test results for methylphenidate

hydrochloride extended-release tablets, a prescription medication for attention deficit and hyperactivity disorder.

By letter dated January 10, 2012, FDA's Office of Regulatory Affairs (ORA) notified Patel of its proposal to debar him for 5 years from providing services in any capacity to a person having an approved or pending drug product application. ORA concluded that Patel should be debarred for 5 years based on the four applicable considerations in section 306(c)(3) of the FD&C Act: (1) the nature and seriousness of his offense, (2) the nature and extent of management participation, (3) the nature and extent of voluntary steps taken to mitigate the impact on the public, and (4) prior convictions involving matters within FDA's jurisdiction. ORA found that the nature and seriousness of the offense, the nature and extent of management participation, the nature and extent of voluntary steps to mitigate the impact on the public were unfavorable factors for Patel. ORA found that the absence of prior convictions involving matters within FDA's jurisdiction was a favorable factor for Patel. ORA concluded, "Weighing all the factors, the Agency has determined that the unfavorable factors far outweigh the favorable factor, and therefore warrant the imposition of a five-year permissible debarment."

In a letter dated January 31, 2012, through counsel, Patel requested a hearing. In a letter dated March 1, 2012, through counsel, Patel submitted a short summary of arguments to support his hearing request.

Under the authority delegated to him by the Commissioner of Food and Drugs, the Director of the Office of Scientific Integrity (OSI) has considered Patel's submission. Hearings are granted only if there is a genuine and substantial issue of fact. Hearings will not be granted on issues of policy or law, on mere allegations, denials or general descriptions of positions and

contentions, or on data and information insufficient to justify the factual determination urged (see 21 CFR 12.24(b)).

OSI has considered Patel's arguments and concludes that Patel's arguments are unpersuasive and fail to raise a genuine and substantial issue of fact requiring a hearing.

II. Arguments

In his hearing request, Patel generally denies: (1) violating good manufacturing practice requirements; (2) violating standard operating procedures by failing to properly investigate, log, and archive questionable, aberrant, and unacceptable laboratory results, so that Able could conceal improprieties and continue to distribute and sell its drug products; (3) manipulating and falsifying testing data and information to conceal from FDA failing laboratory results relating to Able's generic drug products; (4) creating and maintaining false, fraudulent, and inaccurate test results to make it appear that drug products had requisite identity, strength, quality, and purity characteristics; and (5) creating and maintaining false, fraudulent, and inaccurate data and records to obtain FDA approval to market new product lines. Patel also denies that he was in a managerial position and asserts that he took voluntary steps to mitigate the impact of his offenses on the public by cooperating with law enforcement officials during the investigation and subsequent prosecution.

It is unclear whether Patel's five enumerated denials are challenges to ORA's finding that he is subject to debarment under section 306(b)(2)(B)(i)(II) of the FD&C Act or its finding with respect to the consideration under section 306(c)(3)(A), the nature and seriousness of his offense. Regardless of how these denials are directed, they do not create a genuine and substantial issue of fact suitable for a hearing. Section 306(l) of the FD&C Act defines conviction a Federal or State court's entry of a judgment of conviction or acceptance of a guilty plea. In pleading guilty,

Patel stated that he was voluntarily entering his guilty plea based on an understanding of the charges listed in the information, which included the factual allegations that he now disputes. The court then entered a judgment of conviction after accepting Patel's guilty plea. By pleading guilty to the charges in the information, Patel has already admitted and been convicted on the basis of the actions he now denies. Patel does not dispute that the court entered a judgment of conviction or that the court accepted his guilty plea and the factual admissions underlying it. Therefore, Patel's denials, whether directed at the Agency's authority to debar him or the appropriateness or period of debarment, fail to raise a genuine and substantial issue of fact warranting a hearing.

Patel next argues that he was not in a managerial role at the time of the offenses and thereby appears to be challenging ORA's finding to the contrary under section 306(c)(3)(B) of the FD&C Act. In the attachment to Patel's plea agreement, Patel stipulated that he "was an organizer, leader, manager or supervisor of the relevant criminal activity." Patel is bound by his stipulation from the criminal proceedings and cannot now deny his managerial role. Further, Patel does not provide any new information that would overcome his stipulation that he was in a managerial role; therefore, OSI concludes that Patel has failed to raise a genuine and substantial issue of fact requiring a hearing with respect to ORA's finding.

Lastly, Patel claims that he took voluntary steps to mitigate the impact on the public by cooperating with law enforcement officials during the investigation and subsequent prosecution of the conduct surrounding his offense. Patel appears to be responding to ORA's finding under section 306(c)(3)(C) of the FD&C Act that there is no information demonstrating such voluntary steps, but he does not provide any specific information or arguments to support his bare assertion that he cooperated with law enforcement officials. His unsupported statement that he took

voluntary steps to mitigate the effect of his offense on the public through cooperation with law enforcement officials does not create a genuine and substantial issue of fact that warrants a hearing.

Based on the factual findings in the proposal to debar and on the record, OSI finds that the proposed 5-year debarment is appropriate. In particular, the nature and seriousness of Patel's offense weighs significantly in favor of debarment. As stated in the proposal to debar, "[His] conduct created a risk of injury, undermined the Agency's oversight of an approved drug product, undermined the development or approval, including the process for development or approval, of a drug product, and seriously undermined the integrity of the Agency's regulation of drug products." The nature and extent of management participation and lack of voluntary steps to mitigate the impact on the public also weigh in favor of debarment. Although Patel does not appear to have prior criminal convictions involving matters within FDA's jurisdiction, this sole favorable factor is not enough to outweigh the factors supporting debarment.

III. Findings and Order

Therefore, the Director of OSI, under section 306(b)(2)(B)(i)(II) of the FD&C Act and under authority delegated to him by the Commissioner of Food and Drugs, finds that: (1) Patel has been convicted of a conspiracy to commit a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act and (2) that the conduct which served as the basis for the conviction undermines the process for the regulation of drugs. FDA has considered the applicable factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment of 5 years is appropriate.

As a result of the foregoing findings, Patel is debarred for 5 years from providing services in any capacity to a person with an approved or pending drug product application under sections

505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] (see 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application, who knowingly uses the services of Patel, in any capacity during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Patel, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Patel during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: September 21, 2018.

George M. Warren,

Director, Office of Scientific Integrity.

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